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(71)(72) Applicants and Inventors: TEIXEIRA MOREIRA, Luciano, José [BR/BR]; Rua São Tomaz de Aquino, 149, CEP-88036-560 Florianopolis, SC (BR). MACHADO PERES, Ricardo [BR/BR]; Rua Lauro Linhares, 689, Bl 04 Apto 203 (BR). SILVEIRA, Pierre, Galvani [BR/BR]; - (BR).

(74) Agent: ANTONINI, Edemar, Soares; Rua Anita Garibaldi, 79, Sala 1003, CEP-88010-500 Florianópolis, SC (BR).

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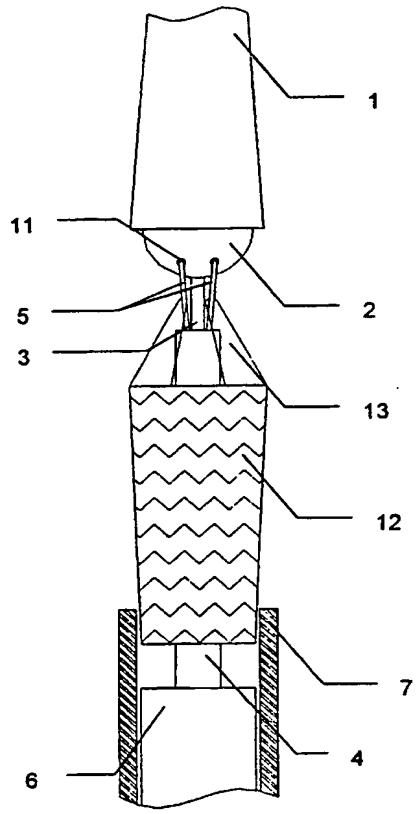
(54) Title: INTRODUCER AND PLACER OF REPAIRS IN TUBULATIONS

(57) Abstract

Introducer and placer of repairs in tubulations is a tubular mechanical device, rigid or flexible, which presents a store place where it is possible to store a tube repair (12), and it presents controls (8, 9) to introduce and to place the repair (12) at the right position in the inner tube wall. The introducer presents an ogive (1) to open the way, niches (4, 6, 7) to store the repair (12), the repair (12) hold system (5, 11), a trigger to set free and to place the repair (12) on the tubulation's right position.



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INTRODUCER AND PLACER OF REPAIRS IN TUBULATIONS

Mechanical device, tubular, with compartment to store tubulation repair and with commands to introduce and to place the repair in a pre-determined point in the tubulation internal wall.

The repair services in hard-accessed tubulations, has been a constant worry to the involved professionals. The leakage caused by perforation in a mansory built-in hydraulic tubulation has required the rupture and withdrawal of part of the wall's revetment. It could be repaired accessing the tubulation's internal wall, through one of the ends. The device proposed in this report is also an alternative in cases of chimney of small diameters, with linkages in specific points throughout the tubulation and it is hard to access through the tubulation's external wall to make a repair. In the medicine field, there is the need of putting repairs, called prothesis, inside the tubulation of the digestive and vascular systems; in this field, there are several types of devices, called catheter, destined to introduction and placement of the prothesis in specific points of the internal wall of veins and arteries.

The introducer and placer of repairs in tubulations, described in this report, consist in a tubular device, rigid or flexible, with external diameter smaller than the tubulation internal diameter; has in one of the ends, space to store the repair and has cables and stem in its interior with access through the other end, for handling and placement of repair in the tubulation.

The figures described below, show the main functional elements of the device. Besides not specifying the dimensions, they don't show the real proportionality of the elements that compose the device. The lack of proportionality in the drawings, is justified because the dimensions and proportion of the elements varies individually according to the application, size, and type of the repair and the tubulation's internal diameter.

The figure 1, shows the device with the ogive(1), the spacer tube(6), the scabbard(7), the maniple(8) of the scabbard(7), the maniple(9) of the spacer tube(6), the trigger(10) and detail(17).

The figure 2 shows the detail(17), with the base(2) of the ogive(1), the guide tube(3), the multilumem tube(4) and the drag wires(5).

The figure 3 shows the base(2) of the ogive(1) with the chain holes(11) of fitting and fixation of the wires(5).

The figure 4 shows the guide tube(3), the multilumem tube(4) and the drag wires(5).

The figure 5 shows detail of the way of cramping the repair(12) in the drag wires(5); the drag wires(5) ends inside the chain holes(11) in the base(2) of the ogive(1); the repair(12) involving the multilumem tube(4) and stored inside the scabbard(7) and aligned with the spacer tube(6). The repair(12) has opening of arches(13) for cramping and fixation in the wires(5).

The figure 6 shows the cut(18), the scabbard(7), the maniple(8) of the scabbard(7), the maniple(9) of the spacer tube(6), and the trigger(10).

The figure 7 shows the cut(18) with the guide tube(3), the multilumem tube(4), the wires(5), and the spacer tube(6).

The figure 8 shows the cut(16), the maniple(9) of the spacer tube(6), the trigger(10) with locking screw(14), and setting point(15) of the wires(15) in the trigger(10).

The figure 9 shows the detail(16) with the multilumem tube(4), the wires(5), and the spacer tube(6).

The figure 10 shows constructive form where the multilumem tube(4) is replaced by

cylindrical tube(19) and connector(20); shows the base(2) of the give(1) with the chain holes (11), the guide tube(3), and the wires(5).

The figure 11 shows the base(2) of the give(1) with the connector(20) set in the base(2). Shows the chaps(21) of the connector(20).

The device is built according to its application, repair type and size, and internal diameter of the tubulation. Special attention is taken in the construction of the end that stores the repair(12). The repair(12) is built-in in the interior of the scabbard(7), involving the multilumem tube(4), occupying the empty of spacer tube(6) and steed by the opening of arches(13) in the drag wires(5). The device is introduced, in the tubulation being repaired, until the repair(12) reaches the section of the tube where the defect is. The positioning can be previewed measuring the distance between the end and the defective section of the tube. The positioning of the repair of the repair can be monitored by X-ray, ultrasound and others. Once positioned the repair in the desired section, make the axial recoil of the scabbard(7) sliding it axially in relation to the spacer tube(6), so the conjunct formed by the ogive(1), guide tube(3), multilumem tube(4), the wires (5), spacer tube(6), and the repair(12) remain still, liberating the repair(12) from its niche. The repair(12) goes through a self-expansion until it presses the internal wall of the tube; the repair(12) is still set, through the opening of arches(13) in the wires(5). During this stage is possible to make an evaluation of the repair(12) positioning related to the section of the tube; if it is necessary to make an adjustment, it is possible to displace axially the repair(12) pushing the conjunct, and specially the ogive(1), forward; the repair(12) moves with the conjunct because of the drag of the wires(5) set in the opening of arches(13) of the repair(12). After the adjustment, is bring into action the trigger(10) that gather the wires(5) inside the multilumem tube(4), disconnecting definitively the repair(12) from the device.

The multilumem tube(4), showed in figures 2, 4, 5, 7, and 9 with straight section in triangular shape, may have the polygonal section with plurality of sides or rounded section. The shape of the section of the multilumem tube(4) depends on the constructive shape of the repair(12), its bending and fittings. The figure 10 shows the tube(19) of rounded section, without longitudinal holes for the passage of the wires(5), replacing the multilumem tube(4). The drag wires(5) run loose in the gap between the guide tube(3) and the flat tube(19); penetrate into the chaps(21) of the connector(20) and point to the chain holes(11) of the base(2).

The axial recoil of the scabbard(7) is obtained manually, keeping still the maniple(9) of the spacer tube(6) and displacing axially the maniple(8) of the scabbard(7) in the direction of the maniple(9) of the spacer tube(6).

The trigger(10) is a rigid stalk-cylindrical piece, placed in the end opposite to the ogive(1); has a small cylindrical surface with external screw(14) that is screwed in the body of the maniple(9) of the spacer tube(6).

The wires(5), that have one of the ends free to set in the opening of arch(13) of the repair(12) and to penetrate in the chain holes(11) of the ogive(1), have the other extremity set in the base(15) of the trigger(10). Bring into action the trigger(10), consists in disconnecting(14) the trigger(10) from the maniple(9) of the spacer tube(6) and displace the trigger(10) axially away from the maniple(9).

Although during the text and drawings, the scabbard is cited and represented as a cylindrical tube with uniform section, it may have geometrically the shape of a tube of scaled diameters. Part of the tube, next to the ogive(1), may have the diameter larger than the scabbard(7) body to store repairs that need big niches.

CLAIMS

1- INTRODUCER AND PLACER OF REPAIRS IN TUBULATIONS particularized by a concentric multilumen device in which its tubes have an independent axial translation, because it owns a central guide tube (3) that holds in one of its edges a conical ogive(1) with a half spherical base(2), because this ogive(1) base(2) has holes (11); because it has a multilumen tube (4) which involves the guide tube (3) that also has holes which matches with the ogive(1) chain holes (11), through those holes cross the drag wires(5) which fit in to the ogive (1) chain holes (11), because it owns a spacer tube (6) that involves the multilumen tube (4) with a cylindrical maniple (9), and it is set at the opposite side of give(1) and there is an axial screw hole; because it owns a scabbard (7) shaped as an external concentric tube, covering the spacer tube (6); the opposite edge (15) of the drag wires (5) are fixed at the cylindrical trigger (10), the trigger (10) has an external screw (14) that fits in to the maniple's (9) screw hole.

2- INTRODUCER AND PLACER OF REPAIRS IN TUBULATIONS according to the claim 1, particularized by the multilumen tube (4) has a triangular flat section, whit three axial holes on the vertexes and another one at the center.

3- INTRODUCER AND PLACER OF REPAIRS IN TUBULATIONS according to the claim 1, particularized by the cylindrical tube (19) and the connector (20), which replace the multilumem tube (4), and the cylindrical tube (19) presents the inner diameter larger than the guide tube (3) external diameter, that make possible the free translation of drag wires (5), between them (19),(3); the cylindrical connector (20) is fixed at the ogive(1) base (2), the connector (20) presents linear chaps (21) and them are aligned with the chain holes (11) of the ogive (1) base (2); and the cylindrical tube (19) is fitted with the connector (20).

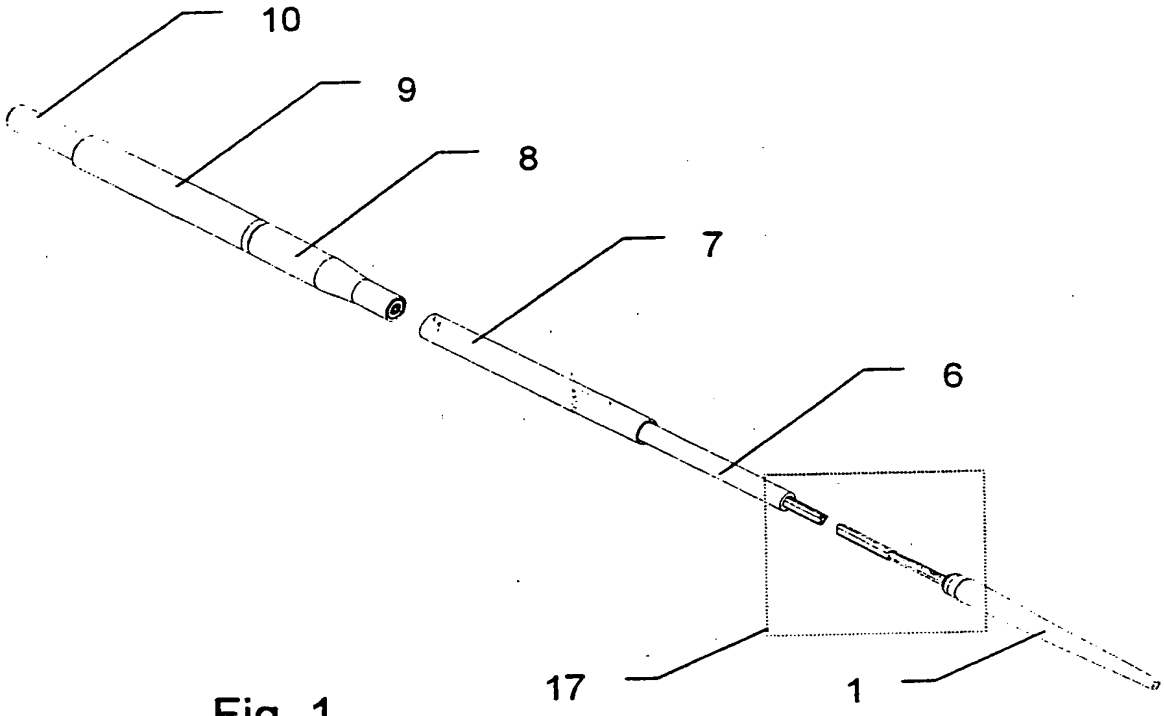

Fig. 1

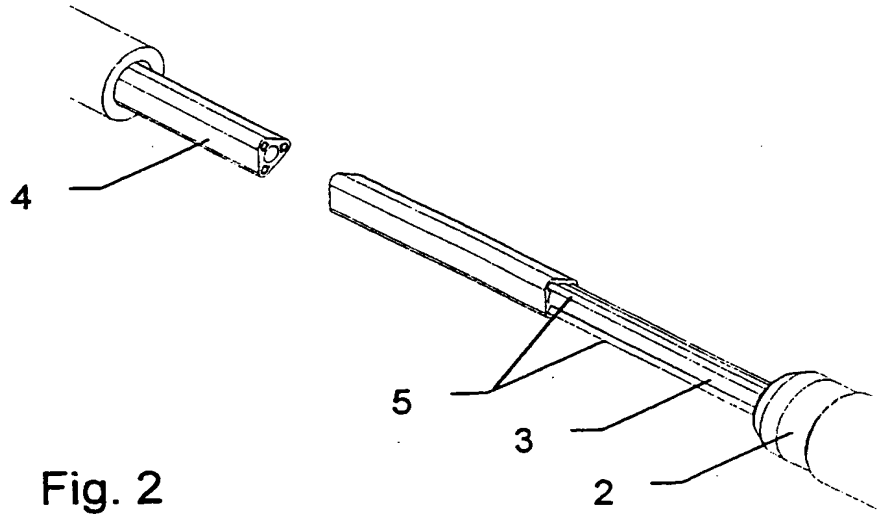

Fig. 2

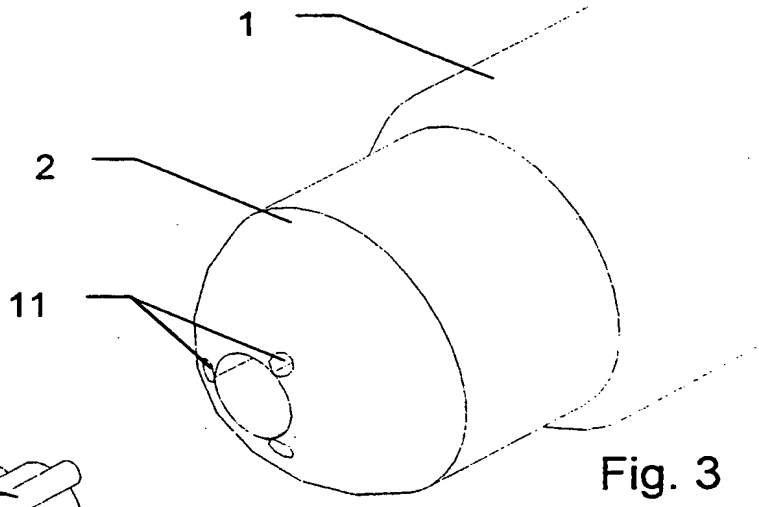

Fig. 3

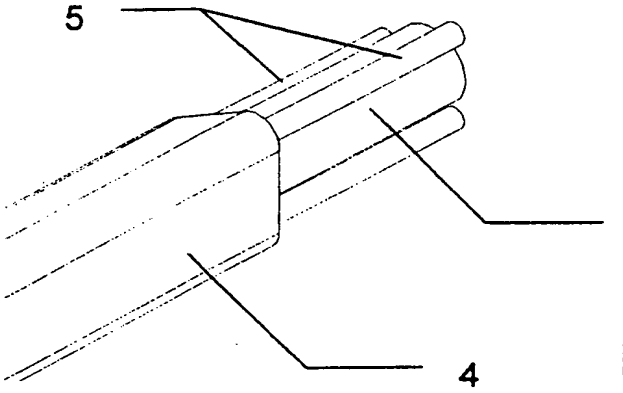

Fig. 4

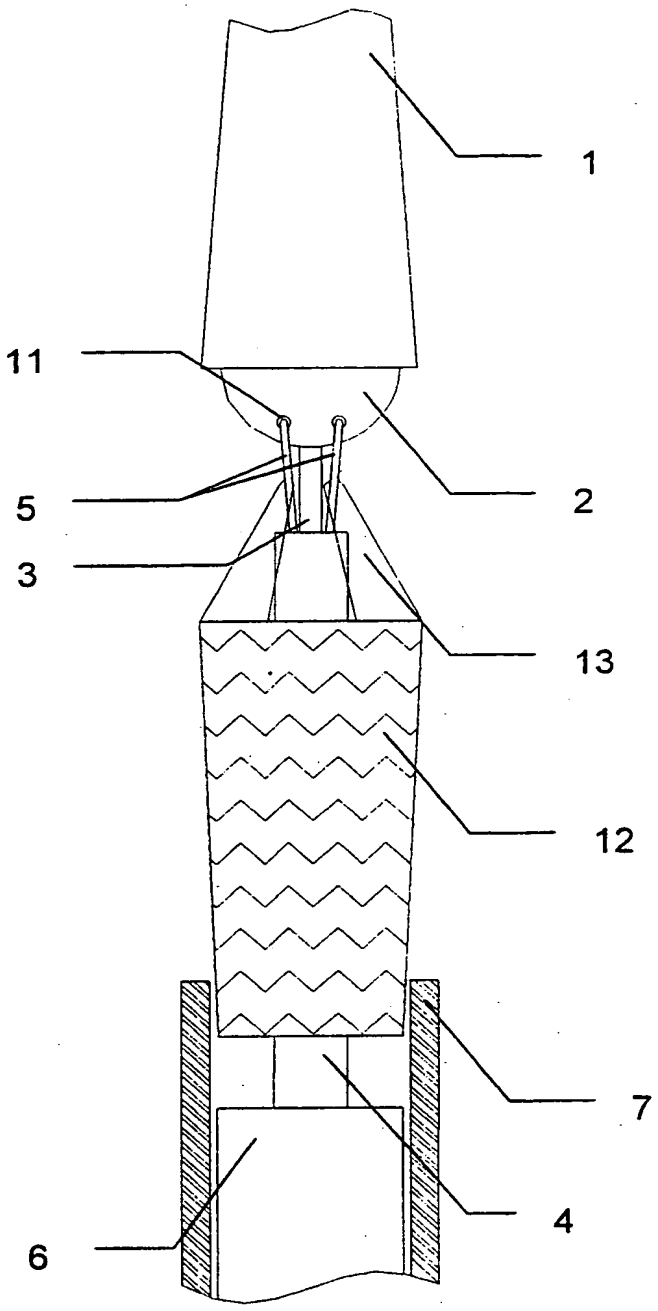

Fig. 5

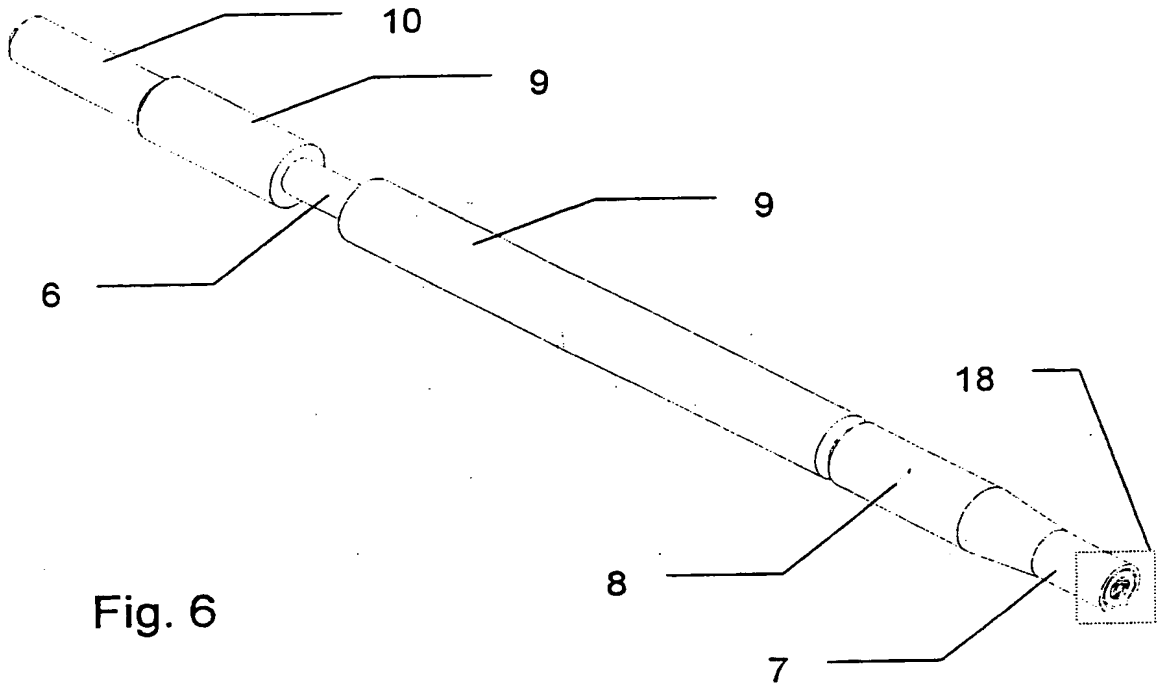

Fig. 6

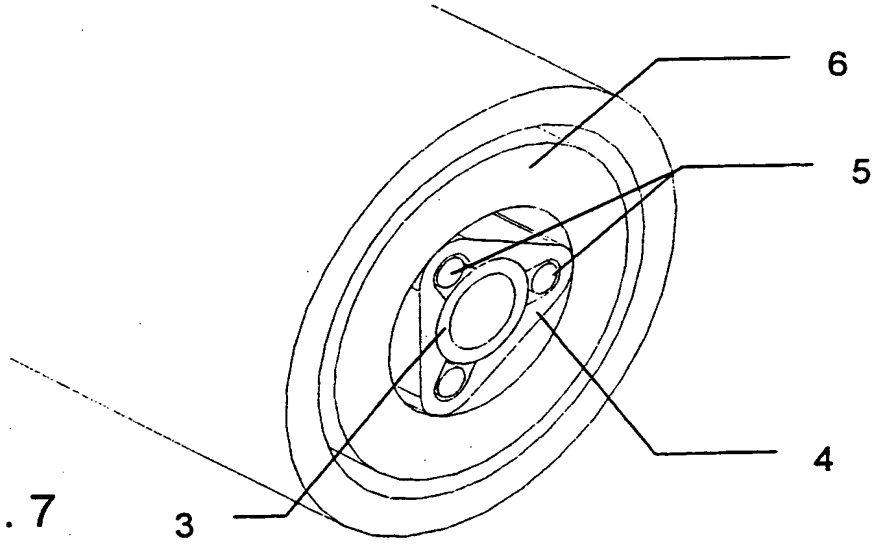

Fig. 7

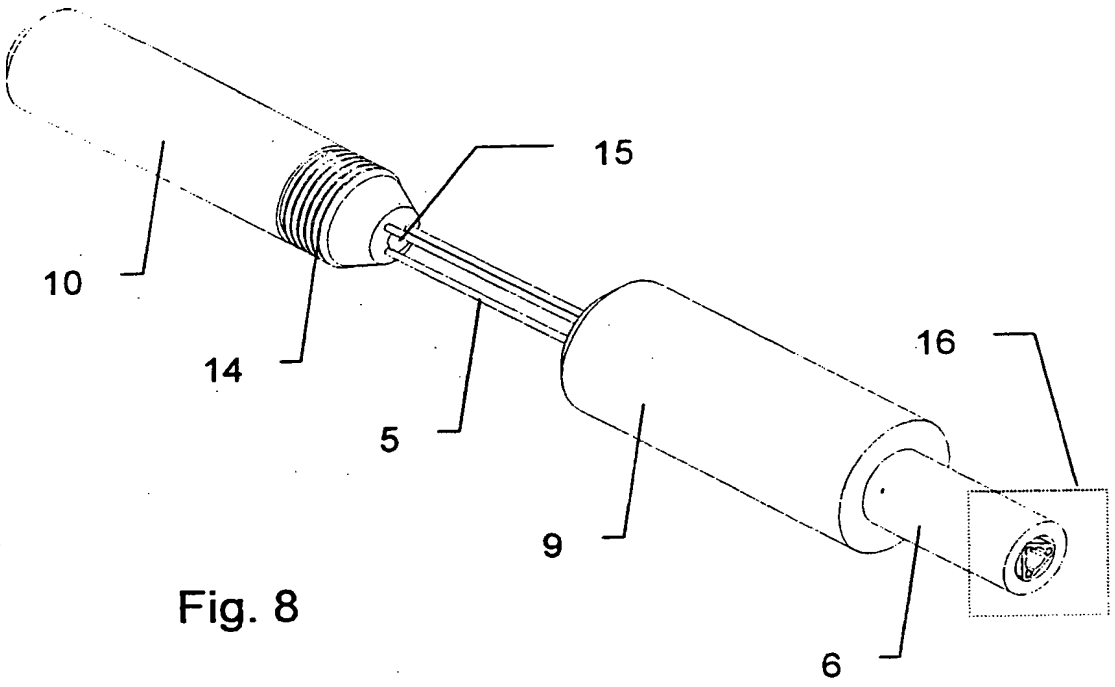

Fig. 8

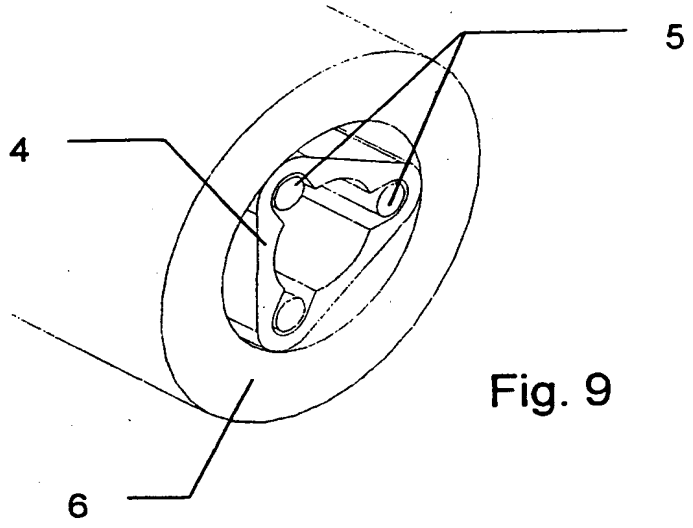

Fig. 9

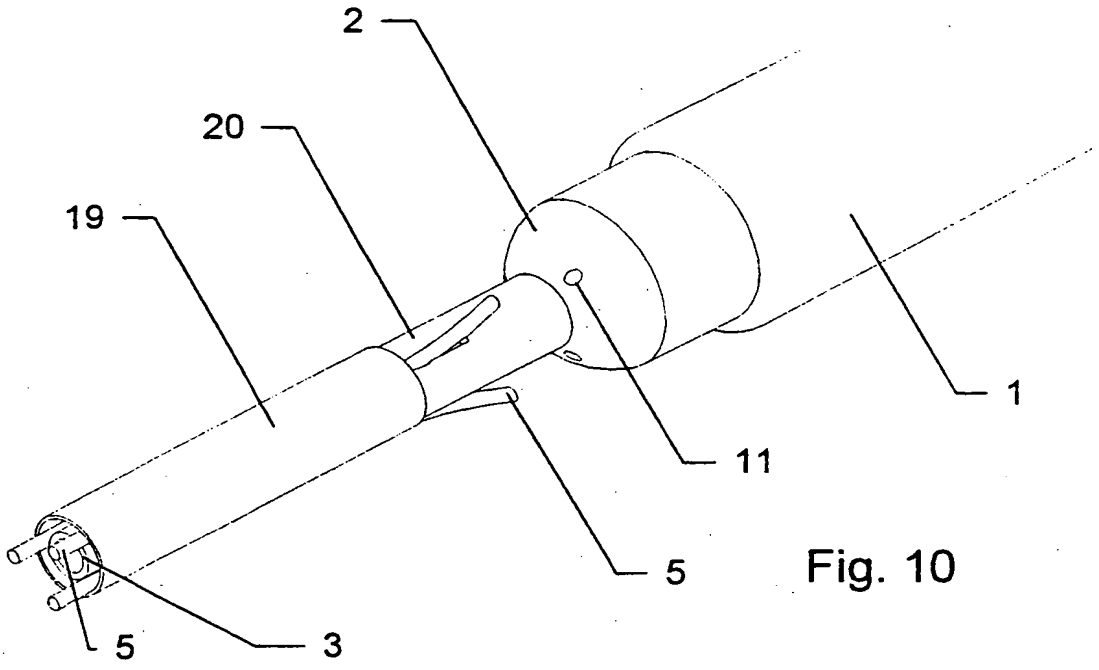

Fig. 10

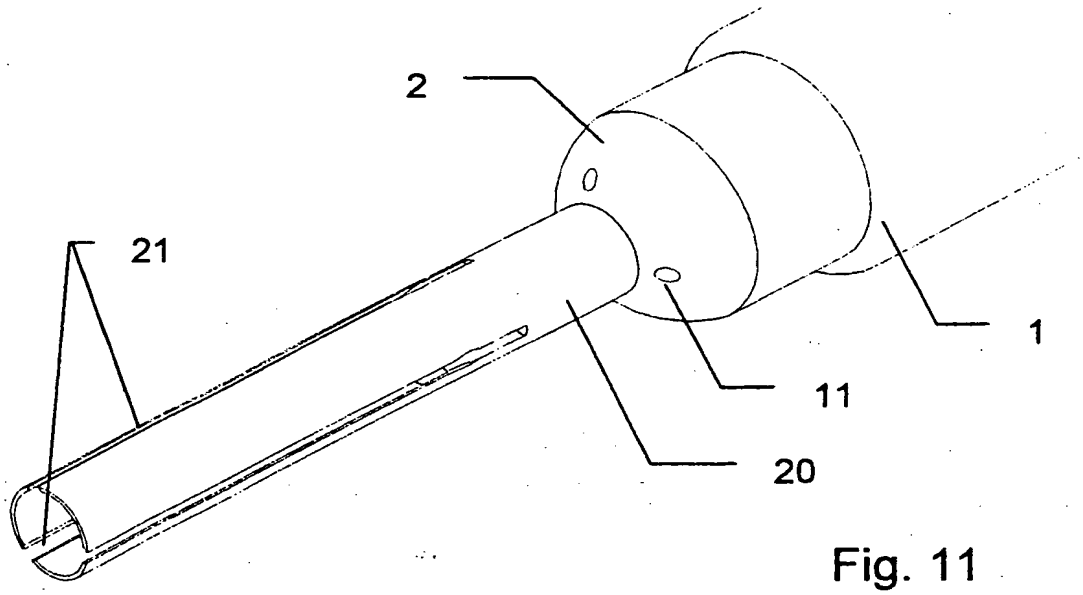

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/BR 00/00042

CLASSIFICATION OF SUBJECT MATTER

IPC[7]: F16L 55/162, A61M 29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC[7]: F16L 55/00, A61M 29/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5683451 A (GLYNN et al.) 4 November 1997 (04.11.97) fig.2, 5-8, 10 [online] [retrieved on 10.8.00]. Retrieved from EPOQUE EPODOC Database.	1-3

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
„A" document defining the general state of the art which is not considered to be of particular relevance
„E" earlier application or patent but published on or after the international filing date
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Date of the actual completion of the international search	Date of mailing of the international search report
10 August 2000 (10.08.2000)	25 September 2000 (25.09.2000)
Name and mailing adress of the ISA/AT Austrian Patent Office Kohlmarkt 8-10; A-1014 Vienna Facsimile No. 1/53424/535	Authorized officer Velinsky-Huber Telephone No. 1/53424/371

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/BR 00/00042

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US A 5683451	04-11-1997	DE U1 29522101	13-01-2000
		DE C0 69518275	14-09-2000
		DE C0 69518435	21-09-2000
		EP A2 686379	13-12-1995
		EP A3 686379	06-03-1996
		EP A2 792627	03-09-1997
		EP A3 792627	12-11-1997
		EP A2 1010406	21-06-2000
		EP B1 686379	09-08-2000
		EP A3 1010406	16-08-2000
		EP B1 792627	16-08-2000
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		US A 5824041	20-10-1998
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		EP A2 943302	22-09-1999
		EP A3 943302	06-10-1999
		EP A1 948946	13-10-1999
		EP B1 696447	19-01-2000
		JP A2 8173548	09-07-1996

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

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in its capacity as elected Office

Date of mailing (day/month/year) 15 February 2001 (15.02.01)	
International application No. PCT/BR00/00042	**Applicant's or agent's file reference**
International filing date (day/month/year) 26 April 2000 (26.04.00)	**Priority date** (day/month/year) 26 April 1999 (26.04.99)
Applicant TEIXEIRA MOREIRA, Luciano, José et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

24 November 2000 (24.11.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
PCT-75		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/BR00/00042	26/04/2000	26/04/1999
International Patent Classification (IPC) or national classification and IPC F16L55/162		
Applicant		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24/11/2000	05.06.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Durrenberger, X Telephone No. +49 89 2399 2755

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/BR00/00042

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, pages:

1-8	as received on	11/05/2001	with letter of	04/05/2001

Claims, No.:

1-5	as received on	11/05/2001	with letter of	04/05/2001

Drawings, sheets:

1/6-6/6	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-5
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-5
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-5
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-A-5683451 (Lenket et al.) 04.11.1997

1). For establishing this reasoned statement, it has been assumed that every feature mentioned under section VIII as essential for the invention is part of the claimed subject-matter of claim 1.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and insofar as this claim can be understood (see section VIII), this document shows the following features thereof (the references in parentheses applying to figure 2 of D1):

a catheter which is an inserter and fitter (30) of tubing repair set (10) comprising a concentric multitubular device (34, 32) with an external tubing (32) inside of which the repair set (10), formed by a radially autoexpansive sleeve and tubular shafts (44, 34) are positioned, the tubular shafts being displaceable relative to each other and relative to the external tubing, a nose cone is attached to the innermost shaft at the distal end of the catheter.

The subject-matter of claim 1 is distinguished from this known catheter by the following features: it comprises a device formed by a set of dragging wires extending axially from a trigger at the proximal end of the catheter to the base of a nose cone at the distal end of the catheter, this dragging wires being suitable to hook up and pull the repair set out of the catheter and loosing it from the mentioned catheter.

These distinguishing features confer novelty to claim 1, claim 1 fulfills the requirements of article 33(2) PCT.

These distinguishing features seem to bring the mentioned technical effect over the prior art: instead of being pushed out the catheter, the repair set is pulled out of the catheter, this permit a better control of the positioning of the repair set during its extraction.

With the reserve mentioned under VIII, as the available prior art does not give a hint upon such an effect, the subject-matter of claim 1 appears to involve an inventive step (Article 33(3) PCT).

2). Claims 2 to 5 are dependent on claim 1 and as their content encompasses the content of claim 1, the objections made under VIII also apply to these claims, nevertheless these claims also meet the requirements of the PCT with respect to novelty and inventive step.

3). The subject-matter of all claims is susceptible of industrial applications (Article 33(4) PCT).

Re Item VII

Certain defects in the international application

1). The amendments filed with the letter dated 04.05.2001 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
in the description, the passage starting page 6, line 20 "Such truncated conical shape..." ending p7 line 1 "less traumatic" describes the effect linked to the shape of the nose cone, the description of this effect is not present in the application as filed, which is contrary to Article 34 (2) b.

2). Claim 5 refers to claim 3, but as claim 5 contains (see the 2nd line of claim 5) the deletion of a feature of claim 3, claim 5 does not contains all the features of claim 3 anymore.
Therefore and according to Rule 6.4 a) PCT, claim 3 is not seen as a claim dependent of claim 1, and is improperly introduced as dependent on claim1 (Rule 6.4 PCT)

Re Item VIII

Certain observations on the international application

1). Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved: "a device to hook up and pull the prothesis out of the catheter and loosing it from the mentioned catheter" This merely amounts to a statement of the underlying problem. The technical features over the set of dragging wires constituting this device are missing from the claimed subject-matter.

2). It is clear from the description, on page 6 lines 9 to 13; on page 7 lines 6 to 10 in connection with the drawing; and on page 6 lines 13 to 14, that the following features are essential to the definition of the invention:

(1) the sheath and the tubular shafts are axially slidable relative to each other,
(2) the tubular shafts are axially slidable relative to each other,
(3) the repair set is radially auto-expansible

Since independent claim 1 does not contain these features, it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

3). Claim 1 is not clear as the connection between the cone nose and the catheter is not defined.

Claim 1 broadly defines the location of the nose cone as "at the catheter distal end".
However, the description and drawings (see figure 5) convey the impression that this features can only be constructed in a particular way, namely by the cone nose is attached to the inserter and fitter by the innermost tubular shaft, and no alternative means are envisaged.

Hence, claim 1 is not supported by the description as required by Article 6 PCT.

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
ELZABURU MARQUEZ, Alberto
Miguel Angel, 21
E - 28010 Madrid
ESPAGNE

ELZABURU Entrada 21.02.01 799103 A|CH

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	20.02.2001
Applicant's or agent's file reference: PCT-75	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/BR00/00042	26/04/2000	26/04/1999

International Patent Classification (IPC) or both national classification and IPC
F16L55/162

Applicant

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain document cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 26/08/2001.

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner
Durrenberger, X

Formalities officer (incl. extension of time limits)
Haase, G
Telephone No. +49 89 2399 7532

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-4 as originally filed

Claims, No.:

1-3 as originally filed

Drawings, sheets:

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrialapplicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	
Inventive step (IS)	Claims	1 to 3
Industrial applicability (IA)	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-A-5683451

1). Insofar as it can be understood (see Section VIII), claim 1 is construed as having the following limiting features:

introducer and placer of repairs in tubulations comprising
a concentric multilumen device,
a plurality of tubes being independently movable in axial translation comprising
a spacer tube,
a multilumen tube located in the spacer tube,
a central guide tube and drag wires located in the passages of the multilumen tube
a conical ogive with a spherical base connected to the central guide tube by the spherical base, the spherical base of the ogive comprising chain holes in which the drag wires are fitted,
a cylindrical maniple comprising an axial screw hole,
a scabbard shaped as an external concentric tube covering the spacer tube,
a cylindrical trigger at which the opposite ends of the drag wires are fixed and having an external screw that fits into the maniple's screw hole.

2). The available state of the art does not show all the precited features of claim 1, the subject-matter of claim 1 is therefore new (Article 33(2) PCT).

3). The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and insofar as this claim can be understood, this document shows the following features thereof (the references in parentheses applying to this document, in particular to figure 2 of D1):

introducer and placer of repairs in tubulations (30) comprising
a concentric multilumen device,
a plurality of tubes (32, 34, 44) being independently movable in axial translation relative to each other comprising
a spacer tube (34),
a central guide tube (44) located in the passage of the spacer tube (34)
an ogive (48) connected to the central guide tube (44)
a cylindrical maniple (52)
a scabbard (32) shaped as an external concentric tube covering the spacer tube (34),
a cylindrical trigger (54)

The subject-matter of claim 1 therefore differs from this known apparatus in that:

- a multilumen tube is located in the spacer tube,
- drag wires are placed in the multilumen tube
- the ogive is conical with a spherical base
- the spherical base of the ogive comprising chain holes in which the drag wires are fitted,
- the cylindrical maniple comprising an axial screw hole, in which the trigger can be fitted

These differences appear not to lead unambiguously (see point VIII) to any specific technical effect, and are therefore regarded as workshop modifications of the apparatus of D1 by the skilled person.

The subject-matter of claim 1 does not involve an inventive step (Article 33(3) PCT).

4). Dependent claim 2 adds a simple constructional feature to the device of claim 1 and appears therefore not to involve an inventive step.

5). Claim 3 refers to claim 1, but is nevertheless construed as an independent claim (see point VII 1).).
The limiting features constituting the subject-matter of claim 3 slightly differ from claim 1, and do not seem to bring any particular technical effect over the prior art (document D1).
Claim 3 does therefore neither involve an inventive step.

Re Item VII
Certain defects in the international application

1). Claim 3 refers to claim 1, but as claim 3 contains (see the 2nd line of claim 3) the replacement of a feature of claim 1 by another feature, claim 3 does not contains all the features of claim 1 anymore.
Therefore and according to Rule 6.4 a) PCT, claim 3 is not seen as a claim dependent of claim 1, and is improperly introduced as dependent on claim1 (Rule 6.4 PCT).

2). Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

3). Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, **with those features known in combination from the prior art (document D1) being placed in the preamble** (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Re Item VIII

Certain observations on the international application

1). As a general remark concerning the lack of clarity of the claims (Article 6 PCT): the features of the claims appear not to be precisely defined in term of constructional features.
Moreover from the wording of claim 1, it is not clear how the present constructional features are positioned relative to each other, and how they cooperate which each other.
These clarity problems lead to the analysis made under V: the present constructional features do not appear to lead to a technical effect over the prior art.

2). The term "involve" used in the claims is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).
For the analysis made under V, it has been assumed that a tube "involving" another tube should be read as a tube located in another tube.

3). In claim 1, it appear to be not clear if the "multilumen device" relate only to the "multilumen tube" or if the multilumen device comprises further elements, leading to a lack of clarity of claim 1 (Article 6 PCT).

4). In the second line of claim 1 the expression "its tubes" is not clear, as no tube has been defined as part of the claimed apparatus before, leading to a lack of clarity of claim 1 (Article 6 PCT).

5). Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The following functional statements " a central guide tube that holds [...] a conical ogive" do not enable the skilled person to determine if the mentioned conical ogive is defined as a part of the subject-matter of

claim 1 or if it is just a part relating to the use of the central guide tube.

To remove this lack of clarity the subject-matter of claim 1 should clearly state which feature are constituting the subject-matter of claim 1.

6). The expression "holes which matches with the ogive chain holes " used in claims 1 is unclear, it leaves the reader in doubt as to if it relates to a corresponding number of holes or to a location of these holes, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT).

7). In claim 1 the part: " because it owns a spacer tube that involves the multilumen tube with a cylindrical maniple, and it is set at the opposite side of the ogive and there is an axial screw hole" is not clear, the location of the different elements relative to each other is not clearly defined (Article 6 PCT), and allows therefore not the reader to understand how the claimed introducer and placer of repairs in tubulation is arranged.

8) Following the remark made under VII 1)., it appears that although claims 1 and 3 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1 and 3 do not meet the requirements of Article 6 PCT.

9). Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves,

and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
ANTONINI, Edemar, Soares
Rua Anita Garibaldi, 79
Sala 1003
CEP-88010-500 Florianópolis, SC
BRÉSIL

Date of mailing (day/month/year) 02 November 2000 (02.11.00)		
Applicant's or agent's file reference		**IMPORTANT NOTICE**
International application No. PCT/BR00/00042	**International filing date** (day/month/year) 26 April 2000 (26.04.00)	**Priority date** (day/month/year) 26 April 1999 (26.04.99)
Applicant TEIXEIRA MOREIRA, Luciano, José et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   EP

   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   02 November 2000 (02.11.00) under No. WO 00/65270

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

Continuation of Form PCT/IB/308

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

Date of mailing (day/month/year)	IMPORTANT NOTICE
02 November 2000 (02.11.00)	
Applicant's or agent's file reference	**International application No.**
	PCT/BR00/00042

The applicant is hereby notified that, at the time of establishment of this Notice, the time limit under Rule 46.1 for making amendments under Article 19 has not yet expired and the International Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
PCT-75		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/BR00/00042	26/04/2000	26/04/1999

International Patent Classification (IPC) or national classification and IPC
F16L55/162

Applicant Teixeira Moreira, Luciano, José et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24/11/2000	05.06.2001

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Durrenberger, X

Telephone No. +49 89 2399 2755

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/BR00/00042

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-8	as received on	11/05/2001	with letter of	04/05/2001

Claims, No.:

1-5	as received on	11/05/2001	with letter of	04/05/2001

Drawings, sheets:

1/6-6/6	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-5
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-5
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-5
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-A-5683451 (Lenket et al.) 04.11.1997

1). For establishing this reasoned statement, it has been assumed that every feature mentioned under section VIII as essential for the invention is part of the claimed subject-matter of claim 1.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and insofar as this claim can be understood (see section VIII), this document shows the following features thereof (the references in parentheses applying to figure 2 of D1):

a catheter which is an inserter and fitter (30) of tubing repair set (10) comprising a concentric multitubular device (34, 32) with an external tubing (32) inside of which the repair set (10), formed by a radially autoexpansive sleeve and tubular shafts (44, 34) are positioned, the tubular shafts being displaceable relative to each other and relative to the external tubing, a nose cone is attached to the innermost shaft at the distal end of the catheter.

The subject-matter of claim 1 is distinguished from this known catheter by the following features: it comprises a device formed by a set of dragging wires extending axially from a trigger at the proximal end of the catheter to the base of a nose cone at the distal end of the catheter, this dragging wires being suitable to hook up and pull the repair set out of the catheter and loosing it from the mentioned catheter.

These distinguishing features confer novelty to claim 1, claim 1 fulfills the requirements of article 33(2) PCT.

These distinguishing features seem to bring the mentioned technical effect over the prior art: instead of being pushed out the catheter, the repair set is pulled out of the catheter, this permit a better control of the positioning of the repair set during its extraction.

With the reserve mentioned under VIII, as the available prior art does not give a hint upon such an effect, the subject-matter of claim 1 appears to involve an inventive step (Article 33(3) PCT).

2). Claims 2 to 5 are dependent on claim 1 and as their content encompasses the content of claim 1, the objections made under VIII also apply to these claims, nevertheless these claims also meet the requirements of the PCT with respect to novelty and inventive step.

3). The subject-matter of all claims is susceptible of industrial applications (Article 33(4) PCT).

Re Item VII

Certain defects in the international application

1). The amendments filed with the letter dated 04.05.2001 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
in the description, the passage starting page 6, line 20 "Such truncated conical shape..." ending p7 line 1 "less traumatic" describes the effect linked to the shape of the nose cone, the description of this effect is not present in the application as filed, which is contrary to Article 34 (2) b.

2). Claim 5 refers to claim 3, but as claim 5 contains (see the 2nd line of claim 5) the deletion of a feature of claim 3, claim 5 does not contains all the features of claim 3 anymore.
Therefore and according to Rule 6.4 a) PCT, claim 3 is not seen as a claim dependent of claim 1, and is improperly introduced as dependent on claim1 (Rule 6.4 PCT)

Re Item VIII
Certain observations on the international application

1). Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved: "a device to hook up and pull the prothesis out of the catheter and loosing it from the mentioned catheter" This merely amounts to a statement of the underlying problem. The technical features over the set of dragging wires constituting this device are missing from the claimed subject-matter.

2). It is clear from the description, on page 6 lines 9 to 13; on page 7 lines 6 to 10 in connection with the drawing; and on page 6 lines 13 to 14, that the following features are essential to the definition of the invention:

(1) the sheath and the tubular shafts are axially slidable relative to each other,
(2) the tubular shafts are axially slidable relative to each other,
(3) the repair set is radially auto-expansible

Since independent claim 1 does not contain these features, it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

3). Claim 1 is not clear as the connection between the cone nose and the catheter is not defined.

Claim 1 broadly defines the location of the nose cone as "at the catheter distal end".
However, the description and drawings (see figure 5) convey the impression that this features can only be constructed in a particular way, namely by the cone nose is attached to the inserter and fitter by the innermost tubular shaft, and no alternative means are envisaged.

Hence, claim 1 is not supported by the description as required by Article 6 PCT.

INSERTER AND FITTER OF TUBING REPAIR SETS

It is related to a tubular shape mechanical device having a receptacle in which a tubing repair set is stored, with controls to insert and fit the repair set at a target place of a tubing inner wall.

Sometimes in medicine there is the necessity of fitting repair sets, called prosthesis, in the blood circulating system tubing or in the digestive system tubing. There already are many apparatus, called catheter, to insert and fit the prosthesis at a specific place in the blood vessels inner wall, veins and other ones. The using of these apparatus together with imaging devices is called treatment or minimum invasive surgery, just because there is no need of submitting the patient to extremely large and traumatic incisions.

The endoprotheses usage by means of the minimum invasive surgery has been increasing lately and presently there are many worldwide enterprises, such as World Manufacturing Corporation and Braile Corporation, that have their own design and that manufacture these apparatus to treat deceases in the vascular system, breathing system or digestive system, that is, the human body tubing systems. Nevertheless, the existing endoprostheses have problems related to positioning, to the fluid flow during its placing, shortening of its length and other ones.

These existing endoprostheses have a small height cylinder shape formed by a sequence of interconnected rings. Each ring being formed by a zigzag bent wire forming a small height cylinder. A collection of these rings are jointed and coated by a biocompatible polymeric fabric. The endoprostheses so manufactured have the characteristic not to offer resistance to axial compression forces. When the small height cylinder, which is the prostheses itself, is submitted to a compression force it is shortened; the rings are juxtaposed due to its wire framed structure.

The existing catheters characterize by having a tubing, here called sheath, inside of which the prosthesis is placed; it is previously radially compressed previously staying like that inside the sheath. A catheter is inserted inside the artery or any other tubing inside the human body. The catheter is inserted until the sheath distal end reaches the point where the prosthesis is to be placed. The prosthesis is then removed from inside the catheter by the action of an existing piston inside the sheath, which pushes the prosthesis out of the sheath. The sheath doesn't move. Pushing the prosthesis out causes an axial compression force on the wired rings that form the prosthesis case. The piston action causes such compression force – the axial force on the prostheses distal end plus the reaction force due to friction caused by the compressed prosthesis against the sheath inner wall. To this reaction force is added the existing obstruction inside the artery. The consequence to this procedure is placing a prosthesis with the length shorter than the desired one and the possibility of fitting it at an inappropriate place. In case this happens, the existing catheters don't have technical resources to replace the prosthesis during its positioning.

Some catheters use the procedure of removing the prosthesis from inside the sheath reverse way, that is, the piston stands still and the sheath that holds the prosthesis is pulled back. As the sheath goes back the prosthesis stands still holded by the piston. While the prosthesis comes out of the sheath, it expands and fits itself at the desired place inside the artery. This procedure shows a technical improvement, as there isn't any prosthesis' axial displacement related to the artery inner wall. Nevertheless, there still is the prosthesis friction related to the catheter sheath inner wall. The prosthesis still is taken out from the catheter by means of a compression force.

Replacing the prosthesis during its positioning still is unviable and traumatic. Once the prosthesis positioning is started, it comes out of the sheath, spreads itself spreading also

the artery. When the first ring, close to the distal end of the small height cylinder, comes out the catheter, it spreads and drowns into the artery inner surface, making any other farther movement difficult. Trying to replace the prosthesis by any axial movement would be difficult on account of the obstruction made by the artery wall.

The action of pushing the prosthesis proximal end is an existing catheters general characteristic and may cause the prosthesis shortening, since the prosthesis comprises wired rings that move one upon the other; it may cause a positioning error because the prosthesis tends to jump from inside the catheter due to the rings spring effect. Difficulties in placing a prosthesis at a definite position has required the unnecessary use of longer prosthesis; this may cause another principal artery branch occlusion.

Patent US 5,683,451 is related to same group of catheter that pushes the prosthesis out of it. It includes a plurality of disposed runners 42 affixed together at one of their proximal ends to one of the shaft 34 ends, which push the prosthesis out of the catheter. The runners 34 remain around the prosthesis 10 reducing its sliding resistance related to the sheath 32 inner wall. Doing this the desired technical effect is withdrawing prosthesis 10 out of inside sheath 32 without shortening it. This is also one of the present report purposes. Another acquired technical effect is a better control over the prosthesis radial expansion process procedure while coming out from inside sheath 32. The runners 42 involving the prosthesis 10 avoid the prosthesis sudden expansion.

While the existing catheters are characterized by pushing the prosthesis out of the catheter, the inserter and fitter of tubing repair sets hereby described is characterized by pulling the prosthesis out of the catheter. The prosthesis is hooked up to the catheter dragging wires. These wires track the prosthesis out of the catheter. The prosthesis distal end, which is hooked up to the dragging wires, stays hooked until the hole prosthesis is out of the catheter

and placed at the target point inside the artery. During the prosthesis manual tracking out of the catheter it is possible to stop the procedure, visualize and check if the positioning place is the correct and desired one or if it is necessary to move the catheter to a new position carrying the prosthesis that still is hold to the catheter by its both ends; the proximal end stays inside the catheter sheath and the distal end stays hooked up to the dragging wires. It is also characterized by having a trigger which holds the prosthesis coupled to the catheter even after the prosthesis withdrawing out of the interior of the catheter. The prosthesis will only be uncoupled from the catheter after the trigger be manually driven.

The inserter and fitter of tubing repair sets hereby described, also called catheter, comprises a tubular device, rigid or flexible, with its outer diameter smaller than the tubing inner diameter; having at its distal end a place to store the repair set, also called prosthesis and having internal cables and rods which can be reached by the opposite side, proximal end, in order to handle and place the repair set inside the tubing.

The figures hereafter described show the device principal functional elements. They don't specify the dimensions and they don't show the real proportionality among the device elements. Not showing proportionality in the drawings is due to the fact that the dimensions and proportionality among the elements vary individually according to the employment, the type and size of the repair set and the tubing inner diameter.

Figure 1 shows the device comprising the nose cone(1), the spacing tubing(6), the sheath(7), the handle(8) of the sheath(7), the handle(9) of the spacing tubing(6), the trigger(10) and the device particular inside spot(17).

Figure 2 shows the device particular inside spot(17) enlarged view comprising the base(2) of the nose cone(1), the core shaft(3), the multilumen(4) tubing and the dragging

wires(5). The multilumen(4) tubing has longitudinal holes through which slide the dragging wires(5).

Figure 3 shows the base(2) of the nose cone(1) with the socket holes(11) to sock the dragging wires(5).

Figure 4 shows the core shaft(3), the multilumen tubing(4) and the dragging wires(5).

Figure 5 shows in detail how the prosthesis(12) is hooked up to the dragging wires(5); the dragging wires(5) distal end is inserted in the socket holes(11) in the base(2) of the nose cone(1); the prosthesis(12) wrapping the multilumen tubing(4) and housed inside the sheath(7) and lined up with the spacing tubing(6). The prosthesis(12) has eyelets(13) to hook up and hold the dragging wires(5).

Figure 6 shows section(18), the sheath(7), the handle(8) of the sheath(7), the handle(9) of the spacing tubing(6) and the trigger(10).

Figure 7 shows section(18) enlarged view with the core shaft(3), the multilumen tubing(4), the dragging wires(5) and the spacing tubing(6).

Figure 8 shows section(16), the handle(9) of the spacing tubing(6), the trigger(10) with the locking screw(14) and the dragging wires(5) fixing spot(15) on the trigger(10).

Figure 9 shows section(16) enlarged view with the multilumen tubing(4), the dragging wires(5) and the spacing tubing(6).

Figure 10 shows a perspective view where the multilumen tubing(4) is replaced by the cylindrical tubing(19) and connector(20); it also shows the base(2) of the nose cone(1) with the socket holes(11), the core shaft(3) and the dragging wires(5).

Figure 11 shows the base(2) of the nose cone(1) with the connector(20) set in the base(2). It shows the chaps(21) of the connector(20).

The repair set is built depending on the employment, type and size of the prosthesis and of the tubing inner diameter. Special attention must be given in building the end point where the prosthesis(12) is going to be stored. The prosthesis(12) is inserted inside the sheath(7), wrapping the multilumen tubing(4), taking the spacing tubing(6) empty space and hooked up through the eyelets(13) to the dragging wires(5). The device is inserted inside the tubing to be repaired, an artery by example, until the prosthesis(12) reaches the tubing damaged place. The delivery distance can be previously set by measuring the distance between the damaged place and the end from which the device is being inserted. Placing the prosthesis(12) can be X-rays, ultrasound or others, monitored. Once the prosthesis is positioned at the target place, the sheath(7) is axially withdrawn sliding axially in relation to the spacing tubing(6), in a way that the unit formed by the nose cone(1), core shaft(3), multilumen tubing(4), dragging wires(5), spacing tubing(6) and the prosthesis(12) stand still, freeing the prosthesis(12) from its housing. The prosthesis(12) starts to expand itself until it pressures the tubing under repair inner wall; the prosthesis(12) stays hooked up to the dragging wires(5) by the eyelets(13). At this procedure phase one can evaluate the prosthesis(12) positioning related to the target place; if it is necessary to adjust something one can axially displace the prosthesis(12) by pushing the hole unit, specially the nose cone(1) forward; the prosthesis(12) displaces itself together with the whole unit due to the dragging wires(5) hooked up to the prosthesis(12) eyelets(13). The nose cone(1) has a truncated conical shape staying over a base(2) with a spherical cap shape. Such truncated conical shape was necessary to easy the catheter inward displacement inside the artery; the base(2) spherical cap shape was necessary to easy the catheter outward displacement together with the prosthesis(12) in the case eventual positioning adjustments are necessary alongside the artery. The nose cone(1) has such aerodynamical shape on both sides of its axis in order to reduce the

device's friction related to the artery inner wall and to make the surgery less traumatic. The base(2) of the nose cone(1) has a number of socket holes(11) radially allocated equal to the number of the existing dragging wires(5) in which the mentioned dragging wires(5) are socked. At the prosthesis(12) placement procedure, the dragging wires(5) - axially allocated inside the prosthesis(12) - go through the eyelets(13) and are socked in the socket holes(11). They stay there even during the coming out of the prosthesis(12) from inside the catheter. The dragging wires(5) loosening from the socket holes(13) happens only when the trigger(10) is driven. When the adjustment is accomplished the trigger(10) is driven and the dragging wires(5) are gathered inside the multilumen(4) tubing, loosing definitely the prosthesis(12) from the device. The multilumen tubing(4) shown in figures 2,4,5,7 and 9 with a cross-section in a triangular shape, may have a polygonal cross-section with many sides or even a circular one. The multilumen tubing(4) cross-section shape depends on how the prosthesis(12) is built, its folding way and sockets. Figure 10 shows the circular cross-section cylindrical tubing(19) without any longitudinal drilling to let the dragging wires(5) pass through in the place of the multilumen tubing(4). The dragging wires(5) go loose inside the portion between the core shaft(3) and the smooth cylindrical tubing(19).

The sheath(7) axial retreat is manually achieved, staying the handle(9) of the spacing tubing(6) still and axially displacing the handle(8) of the sheath(7) in direction of the mentioned handle(9) of the spacing tubing(6).

The trigger(10) is a cylindrical rigid handle located at the catheter proximal end; it has a locking screw(14) which is an external threaded short cylindrical surface, that is screwed to the body of the mentioned handle(9) of the spacing tubing(6).

The dragging wires(5), that have their distal end free to be holded by the eyelets(13) of the prosthesis(12) in order to sock in the holes(11) of the nose cone(1), have their proximal

end fixed to the base(15) of the trigger(10). Driving the trigger(10) means unscrewing the locking screw(14) of the trigger(10) from the handle(9) of the spacing tubing(6) and axially displace the trigger(10) away from the mentioned handle(9).

Although in the report text and in the figures the sheath(7) is mentioned and shown as a uniform cross-section cylindrical tubing, it can have the geometric shape of a staggered diameters tubing. The staggered tubing end near the nose cone(1) may have the diameter larger than the sheath(7) body in order to house the prostheses that need bigger housing.

CLAIMS

1 – INSERTER AND FITTER OF TUBING REPAIR SETS comprising a concentric multitubular device called catheter with an external tubing called sheath(7) inside of which there is the repair set called prosthesis(12) and the tubular shafts(3)(6), characterized by having a device to hook up and pull the prosthesis out of the catheter and loosing it related to the mentioned catheter, formed by a set of dragging wires(5) axially allocated since the trigger(10) at the proximal catheter end up to base(2) of the nose cone(1) at the catheter distal end.

2 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 1, characterized by having the base(2) of the nose cone(1) a number of socket holes(11) radially allocated equal to the number of dragging wires(5).

3 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 1, characterized by the set of dragging wires(5) being affixed to the trigger(10), positioned inside of a multilumen tubing(4); and the said unit formed by the multilumen tubing(4) and the dragging wires(5) going axially through inside the prosthesis(12) and when they come out of the prosthesis(12) the dragging wires(5) are holded by the eyelets(13) of the prosthesis(12); the dragging wires(5) distal ends are then socked into the socket holes(11) on the base(2) of the nose cone(1).

4 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 3, characterized by the said trigger(10) being screwed (14) to the handle(9) of the spacing tubing(6) and being able of loosing itself and drag axially backwards the dragging wires(5) and the so mentioned dragging wires(5) loosing themselves from the base(2) of the nose cone(1) and from the eyelets(13) of the prosthesis(12).

5 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 3, characterized by the said dragging wires(5), without the multilumen tubing(4), being axially allocated between the spacing tubing(6) and the core shaft(3), and having the catheter at the sheath(7) distal end a connector(20); having the said connector(20) a number of longitudinal grooves(21) equal to the number of the existing dragging wires(5).

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INSERTER AND FITTER OF TUBING REPAIR SETS

It is related to a tubular shape mechanical device having a receptacle in which a tubing repair set is stored, with controls to insert and fit the repair set at a target place of a tubing inner wall.

Sometimes in medicine there is the necessity of fitting repair sets, called prosthesis, in the blood circulating system tubing or in the digestive system tubing. There already are many apparatus, called catheter, to insert and fit the prosthesis at a specific place in the blood vessels inner wall, veins and other ones. The using of these apparatus together with imaging devices is called treatment or minimum invasive surgery, just because there is no need of submitting the patient to extremely large and traumatic incisions.

The endoprotheses usage by means of the minimum invasive surgery has been increasing lately and presently there are many worldwide enterprises, such as World Manufacturing Corporation and Braile Corporation, that have their own design and that manufacture these apparatus to treat deceases in the vascular system, breathing system or digestive system, that is, the human body tubing systems. Nevertheless, the existing endoprostheses have problems related to positioning, to the fluid flow during its placing, shortening of its length and other ones.

These existing endoprostheses have a small height cylinder shape formed by a sequence of interconnected rings. Each ring being formed by a zigzag bent wire forming a small height cylinder. A collection of these rings are jointed and coated by a biocompatible polymeric fabric. The endoprostheses so manufactured have the characteristic not to offer resistance to axial compression forces. When the small height cylinder, which is the prostheses itself, is submitted to a compression force it is shortened; the rings are juxtaposed due to its wire framed structure.

The existing catheters characterize by having a tubing, here called sheath, inside of which the prosthesis is placed; it is previously radially compressed previously staying like that inside the sheath. A catheter is inserted inside the artery or any other tubing inside the human body. The catheter is inserted until the sheath distal end reaches the point where the prosthesis is to be placed. The prosthesis is then removed from inside the catheter by the action of an existing piston inside the sheath, which pushes the prosthesis out of the sheath. The sheath doesn't move. Pushing the prosthesis out causes an axial compression force on the wired rings that form the prosthesis case. The piston action causes such compression force – the axial force on the prostheses distal end plus the reaction force due to friction caused by the compressed prosthesis against the sheath inner wall. To this reaction force is added the existing obstruction inside the artery. The consequence to this procedure is placing a prosthesis with the length shorter than the desired one and the possibility of fitting it at an inappropriate place. In case this happens, the existing catheters don't have technical resources to replace the prosthesis during its positioning.

Some catheters use the procedure of removing the prosthesis from inside the sheath reverse way, that is, the piston stands still and the sheath that holds the prosthesis is pulled back. As the sheath goes back the prosthesis stands still holded by the piston. While the prosthesis comes out of the sheath, it expands and fits itself at the desired place inside the artery. This procedure shows a technical improvement, as there isn't any prosthesis' axial displacement related to the artery inner wall. Nevertheless, there still is the prosthesis friction related to the catheter sheath inner wall. The prosthesis still is taken out from the catheter by means of a compression force.

Replacing the prosthesis during its positioning still is unviable and traumatic. Once the prosthesis positioning is started, it comes out of the sheath, spreads itself spreading also

the artery. When the first ring, close to the distal end of the small height cylinder, comes out the catheter, it spreads and drowns into the artery inner surface, making any other farther movement difficult. Trying to replace the prosthesis by any axial movement would be difficult on account of the obstruction made by the artery wall.

The action of pushing the prosthesis proximal end is an existing catheters general characteristic and may cause the prosthesis shortening, since the prosthesis comprises wired rings that move one upon the other; it may cause a positioning error because the prosthesis tends to jump from inside the catheter due to the rings spring effect. Difficulties in placing a prosthesis at a definite position has required the unnecessary use of longer prosthesis; this may cause another principal artery branch occlusion.

Patent US 5,683,451 is related to same group of catheter that pushes the prosthesis out of it. It includes a plurality of disposed runners 42 affixed together at one of their proximal ends to one of the shaft 34 ends, which push the prosthesis out of the catheter. The runners 34 remain around the prosthesis 10 reducing its sliding resistance related to the sheath 32 inner wall. Doing this the desired technical effect is withdrawing prosthesis 10 out of inside sheath 32 without shortening it. This is also one of the present report purposes. Another acquired technical effect is a better control over the prosthesis radial expansion process procedure while coming out from inside sheath 32. The runners 42 involving the prosthesis 10 avoid the prosthesis sudden expansion.

While the existing catheters are characterized by pushing the prosthesis out of the catheter, the inserter and fitter of tubing repair sets hereby described is characterized by pulling the prosthesis out of the catheter. The prosthesis is hooked up to the catheter dragging wires. These wires track the prosthesis out of the catheter. The prosthesis distal end, which is hooked up to the dragging wires, stays hooked until the hole prosthesis is out of the catheter

and placed at the target point inside the artery. During the prosthesis manual tracking out of the catheter it is possible to stop the procedure, visualize and check if the positioning place is the correct and desired one or if it is necessary to move the catheter to a new position carrying the prosthesis that still is hold to the catheter by its both ends; the proximal end stays inside the catheter sheath and the distal end stays hooked up to the dragging wires. It is also characterized by having a trigger which holds the prosthesis coupled to the catheter even after the prosthesis withdrawing out of the interior of the catheter. The prosthesis will only be uncoupled from the catheter after the trigger be manually driven.

The inserter and fitter of tubing repair sets hereby described, also called catheter, comprises a tubular device, rigid or flexible, with its outer diameter smaller than the tubing inner diameter; having at its distal end a place to store the repair set, also called prosthesis and having internal cables and rods which can be reached by the opposite side, proximal end, in order to handle and place the repair set inside the tubing.

The figures hereafter described show the device principal functional elements. They don't specify the dimensions and they don't show the real proportionality among the device elements. Not showing proportionality in the drawings is due to the fact that the dimensions and proportionality among the elements vary individually according to the employment, the type and size of the repair set and the tubing inner diameter.

Figure 1 shows the device comprising the nose cone(1), the spacing tubing(6), the sheath(7), the handle(8) of the sheath(7), the handle(9) of the spacing tubing(6), the trigger(10) and the device particular inside spot(17).

Figure 2 shows the device particular inside spot(17) enlarged view comprising the base(2) of the nose cone(1), the core shaft(3), the multilumen(4) tubing and the dragging

wires(5). The multilumen(4) tubing has longitudinal holes through which slide the dragging wires(5).

Figure 3 shows the base(2) of the nose cone(1) with the socket holes(11) to sock the dragging wires(5).

Figure 4 shows the core shaft(3), the multilumen tubing(4) and the dragging wires(5).

Figure 5 shows in detail how the prosthesis(12) is hooked up to the dragging wires(5); the dragging wires(5) distal end is inserted in the socket holes(11) in the base(2) of the nose cone(1); the prosthesis(12) wrapping the multilumen tubing(4) and housed inside the sheath(7) and lined up with the spacing tubing(6). The prosthesis(12) has eyelets(13) to hook up and hold the dragging wires(5).

Figure 6 shows section(18), the sheath(7), the handle(8) of the sheath(7), the handle(9) of the spacing tubing(6) and the trigger(10).

Figure 7 shows section(18) enlarged view with the core shaft(3), the multilumen tubing(4), the dragging wires(5) and the spacing tubing(6).

Figure 8 shows section(16), the handle(9) of the spacing tubing(6), the trigger(10) with the locking screw(14) and the dragging wires(5) fixing spot(15) on the trigger(10).

Figure 9 shows section(16) enlarged view with the multilumen tubing(4), the dragging wires(5) and the spacing tubing(6).

Figure 10 shows a perspective view where the multilumen tubing(4) is replaced by the cylindrical tubing(19) and connector(20); it also shows the base(2) of the nose cone(1) with the socket holes(11), the core shaft(3) and the dragging wires(5).

Figure 11 shows the base(2) of the nose cone(1) with the connector(20) set in the base(2). It shows the chaps(21) of the connector(20).

The repair set is built depending on the employment, type and size of the prosthesis and of the tubing inner diameter. Special attention must be given in building the end point where the prosthesis(12) is going to be stored. The prosthesis(12) is inserted inside the sheath(7), wrapping the multilumen tubing(4), taking the spacing tubing(6) empty space and hooked up through the eyelets(13) to the dragging wires(5). The device is inserted inside the tubing to be repaired, an artery by example, until the prosthesis(12) reaches the tubing damaged place. The delivery distance can be previously set by measuring the distance between the damaged place and the end from which the device is being inserted. Placing the prosthesis(12) can be X-rays, ultrasound or others, monitored. Once the prosthesis is positioned at the target place, the sheath(7) is axially withdrawn sliding axially in relation to the spacing tubing(6), in a way that the unit formed by the nose cone(1), core shaft(3), multilumen tubing(4), dragging wires(5), spacing tubing(6) and the prosthesis(12) stand still, freeing the prosthesis(12) from its housing. The prosthesis(12) starts to expand itself until it pressures the tubing under repair inner wall; the prosthesis(12) stays hooked up to the dragging wires(5) by the eyelets(13). At this procedure phase one can evaluate the prosthesis(12) positioning related to the target place; if it is necessary to adjust something one can axially displace the prosthesis(12) by pushing the hole unit, specially the nose cone(1) forward; the prosthesis(12) displaces itself together with the whole unit due to the dragging wires(5) hooked up to the prosthesis(12) eyelets(13). The nose cone(1) has a truncated conical shape staying over a base(2) with a spherical cap shape. Such truncated conical shape was necessary to easy the catheter inward displacement inside the artery; the base(2) spherical cap shape was necessary to easy the catheter outward displacement together with the prosthesis(12) in the case eventual positioning adjustments are necessary alongside the artery. The nose cone(1) has such aerodynamical shape on both sides of its axis in order to reduce the

device's friction related to the artery inner wall and to make the surgery less traumatic. The base(2) of the nose cone(1) has a number of socket holes(11) radially allocated equal to the number of the existing dragging wires(5) in which the mentioned dragging wires(5) are socked. At the prosthesis(12) placement procedure, the dragging wires(5) - axially allocated inside the prosthesis(12) - go through the eyelets(13) and are socked in the socket holes(11). They stay there even during the coming out of the prosthesis(12) from inside the catheter. The dragging wires(5) loosening from the socket holes(13) happens only when the trigger(10) is driven. When the adjustment is accomplished the trigger(10) is driven and the dragging wires(5) are gathered inside the multilumen(4) tubing, loosing definitely the prosthesis(12) from the device. The multilumen tubing(4) shown in figures 2,4,5,7 and 9 with a cross-section in a triangular shape, may have a polygonal cross-section with many sides or even a circular one. The multilumen tubing(4) cross-section shape depends on how the prosthesis(12) is built, its folding way and sockets. Figure 10 shows the circular cross-section cylindrical tubing(19) without any longitudinal drilling to let the dragging wires(5) pass through in the place of the multilumen tubing(4). The dragging wires(5) go loose inside the portion between the core shaft(3) and the smooth cylindrical tubing(19).

The sheath(7) axial retreat is manually achieved, staying the handle(9) of the spacing tubing(6) still and axially displacing the handle(8) of the sheath(7) in direction of the mentioned handle(9) of the spacing tubing(6).

The trigger(10) is a cylindrical rigid handle located at the catheter proximal end; it has a locking screw(14) which is an external threaded short cylindrical surface, that is screwed to the body of the mentioned handle(9) of the spacing tubing(6).

The dragging wires(5), that have their distal end free to be holded by the eyelets(13) of the prosthesis(12) in order to sock in the holes(11) of the nose cone(1), have their proximal

end fixed to the base(15) of the trigger(10). Driving the trigger(10) means unscrewing the locking screw(14) of the trigger(10) from the handle(9) of the spacing tubing(6) and axially displace the trigger(10) away from the mentioned handle(9).

Although in the report text and in the figures the sheath(7) is mentioned and shown as a uniform cross-section cylindrical tubing, it can have the geometric shape of a staggered diameters tubing. The staggered tubing end near the nose cone(1) may have the diameter larger than the sheath(7) body in order to house the prostheses that need bigger housing.

CLAIMS

1 – INSERTER AND FITTER OF TUBING REPAIR SETS comprising a concentric multitubular device called catheter with an external tubing called sheath(7) inside of which there is the repair set called prosthesis(12) and the tubular shafts(3)(6), characterized by having a device to hook up and pull the prosthesis out of the catheter and loosing it related to the mentioned catheter, formed by a set of dragging wires(5) axially allocated since the trigger(10) at the proximal catheter end up to base(2) of the nose cone(1) at the catheter distal end.

2 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 1, characterized by having the base(2) of the nose cone(1) a number of socket holes(11) radially allocated equal to the number of dragging wires(5).

3 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 1, characterized by the set of dragging wires(5) being affixed to the trigger(10), positioned inside of a multilumen tubing(4); and the said unit formed by the multilumen tubing(4) and the dragging wires(5) going axially through inside the prosthesis(12) and when they come out of the prosthesis(12) the dragging wires(5) are holded by the eyelets(13) of the prosthesis(12); the dragging wires(5) distal ends are then socked into the socket holes(11) on the base(2) of the nose cone(1).

4 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 3, characterized by the said trigger(10) being screwed (14) to the handle(9) of the spacing tubing(6) and being able of loosing itself and drag axially backwards the dragging wires(5) and the so mentioned dragging wires(5) loosing themselves from the base(2) of the nose cone(1) and from the eyelets(13) of the prosthesis(12).

5 - INSERTER AND FITTER OF TUBING REPAIR SETS as claimed in claim 3, characterized by the said dragging wires(5), without the multilumen tubing(4), being axially allocated between the spacing tubing(6) and the core shaft(3), and having the catheter at the sheath(7) distal end a connector(20); having the said connector(20) a number of longitudinal grooves(21) equal to the number of the existing dragging wires(5).